



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,298	06/27/2003	Paola LaColla	IDX 1017 US 06171.105078	9201
57263	7590	08/24/2007	EXAMINER	
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	
			MAIL DATE	DELIVERY MODE
			08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/609,298	Applicant(s) LACOLLA ET AL.	
	Examiner Traviss C. McIntosh	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,17-25,43-55 and 62-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12,17-25,43-55 and 62-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/07 & 8/7/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed 5/21/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 11, 21, 54-55, and 62-65 have been amended.

Claims 66-71 have been added.

Claims 1-10, 13-16, 26-42, and 56-61 have been canceled.

Remarks drawn to rejections of Office Action mailed 8/2/2006 include:

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

Double Patenting Rejections: which has been maintained for reasons of record.

An action on the merits of claims 11-12, 17-25, 43-55, and 62-71 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office Action.

Double Patenting

The rejection of claims 11-12, 17-25, 43-55, and 62-65 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,812,219 is maintained for reasons of record. Newly added claims 65-71 are rejected for the

Art Unit: 1623

same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating flavivirus infections in a host using 2'-methyl-pyrimidine nucleosides. It is noted that the instant application requires a 3'-amino acid moiety, and the '219 patent comprises H or phosphate at the 3' and 5 positions, however, the '219 patents claims are also drawn to "or prodrugs thereof", and the amino acids instantly claimed are art known prodrugs. One of skill in the art would find it obvious that these groups are substantially overlapping.

Applicants argue that the '219 patent is silent to the use of the instantly claimed 3'-amino-acid ester prodrugs, however, it is noted that the '219 patent's claims encompass esters or prodrugs thereof. It would be obvious to make a 3'-amino acid ester prodrug of the '219 patent's claims absent unexpected results, as amino acid esters are known to make prodrugs. Obviousness based on similarity of structure and function entails motivation to make claimed compound in the expectation that compounds similar in structure will have similar properties. Where the prior art compounds essentially bracket the claimed compounds and are known to be effective as well known pesticides, for example, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. See *In re Payne*, 606 F.2d 303, 203 USPQ 245, 254-55 (CCPA 1979). Prodrug esters are well known in the art, as are amino acid prodrug esters, as such, absent unexpected results, the examiner believes it would be obvious to make 3'-amino-acid prodrug esters of the '219 patent's compounds.

Art Unit: 1623

The rejection of claims 11-12, 17-25, 43-55, and 62-65 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,914,054 is maintained for reasons of record. Newly added claims 65-71 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating flavivirus infections in a host using 2'-methyl-pyrimidine nucleoside. While the '054 patent is drawn to treating HCV, it is known that HCV is a flavivirus, and applicants even limit their methods in the instant application to treating HCV (see claim 12), as such, methods of treating flavivirus and HCV are seen to be obvious over each other. Moreover, it is noted that the instant application requires compounds which comprise a 3'-amino acid ester prodrug moiety, and the '054 patent comprises H at the 3' position, however, the '054 patents claims are also drawn to "or esters thereof. One of skill in the art would find it obvious that these groups are substantially overlapping.

Applicants argue that the '054 patent is silent to the use of the instantly claimed 3'-amino-acid esters, however, the '054 patent's claims can also be esters or prodrugs thereof. It would be obvious to make a 3'-amino acid ester prodrug of the '054 patent's claims absent unexpected results, as amino acid esters are known to make prodrugs. Obviousness based on similarity of structure and function entails motivation to make claimed compound in the expectation that compounds similar in structure will have similar properties. Where the prior art compounds essentially bracket the claimed compounds and are known to be effective as well known pesticides, for example, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. See *In re Payne*, 606 F.2d 303, 203 USPQ

Art Unit: 1623

245, 254-55 (CCPA 1979). Prodrug esters are well known in the art, as are amino acid prodrug esters, as such, absent unexpected results, the examiner believes it would be obvious to make 3'-amino-acid prodrug esters of the '054 patent's compounds.

Claims 11-12, 17-25, 43-55, and 62-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3, 8-17, and 19-66 of copending Application No. 11/005,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods of treating flavivirus infections using overlapping 2'-methyl pyrimidine nucleosides which have 3'-amino acid prodrug moieties. It would be obvious to one of skill in the art that these applications are claiming substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-12, 17-25, 43-55, and 62-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 8-17, 19-21, 25, 29-37, 39, and 52 of copending Application No. 11/005,440. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods of treating flavivirus infections or HCV using overlapping 2'-alkyl pyrimidine nucleosides which comprise 3'-amino acid prodrug moieties.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1623

Claims 11-12, 17-25, 43-55, and 62-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 130-131 and 137-149 of copending Application No. 10/602,691. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods of treating HCV using overlapping 2'-methyl pyrimidine nucleosides. It is obvious that the instant application and the '691 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-12, 17-25, 43-55, and 62-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 8-17 and 19-57 of copending Application No. 11/005,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides. It is obvious that the instant application and the '446 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-12, 17-25, 43-55, and 62-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 8-18 of US Patent No. 7,105,493. Although the conflicting claims are not identical, they are not patentably distinct

Art Unit: 1623

from each other because both applications are drawn to methods of treating flavivirus infections by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides, or prodrug or esters thereof. It would be obvious to make a the claimed 3'-amino acid ester prodrugs of the '493 patent's claims absent unexpected results, as amino acid esters are known to make prodrugs. Obviousness based on similarity of structure and function entails motivation to make claimed compound in the expectation that compounds similar in structure will have similar properties. Where the prior art compounds essentially bracket the claimed compounds and are known to be effective as well known pesticides, for example, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. See *In re Payne*, 606 F.2d 303, 203 USPQ 245, 254-55 (CCPA 1979). Prodrug esters are well known in the art, as are amino acid prodrug esters, as such, absent unexpected results, the examiner believes it would be obvious to make 3'-amino-acid prodrug esters of the '493 patent's compounds.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
August 20, 2007

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623

 8/20/07